February 6, 2003

MEMORANDUM

SUBJECT: Transmittal of the Meeting Minutes of the Endocrine Disruptor Methods Validation Subcommittee under the National Advisory Council for Environmental Policy and Technology (NACEPT), held December 4, 2002.

TO: Dorothy Bowers, Chair
National Advisory Council for Environmental Policy and Technology
Office of Cooperation and Environmental Management
And
Gwen Whitt, Designated Federal Official
National Advisory Council for Environmental Policy and Technology
Office of Cooperation and Environmental Management

FROM: Jane Scott Smith, Designated Federal Official /s/
NACEPT Endocrine Disruptor Methods Validation Subcommittee
Office of Science Coordination and Policy/OPPTS

THRU: Joseph Merenda, Director /s/
Chair of Endocrine Disruptor Methods Validation Subcommittee
Office of Science Coordination and Policy/OPPTS

Please find attached the minutes of the NACEPT Endocrine Disruptor Methods Validation Subcommittee sixth open meeting that was conducted as the second teleconference and held in Washington, D.C. December 4, 2002. The focus of this meeting was a Detailed Review Paper (DRP), on the Fish Lifecycle Assay.

Information about NACEPT EDMVS meetings and activities can be obtained from the website at http://www.epa.gov/scipoly/oscpendo, the OPPT Docket, [OPPT 2002-0059] at (202) 566-0280, or by going to www.epa.gov/epahome/dockets.htm and searching for OPPT-2002-0059. Interested persons are invited to contact Jane Smith, EDMVS Designated Federal Official (DFO), via e-mail at smith.jane-scott@epa.gov.

cc:

Sonia Altieri
Charles Auer
Daiva Balkus
Dennis Deziel
Susan Hazen
Stephen Johnson
James Jones
William Jordan
Marcia Mulkey
Margaret Schneider
Adam Sharp
OPPT Docket 2002-0059

MEETING MINUTES
OF
ENDOCRINE DISRUPTOR METHODS VALIDATION SUBCOMMITTEE
A Subcommittee of The National Advisory Council for
Environmental Policy and Technology

TELECONFERENCE ON
DECEMBER 4, 2002
AT
RESOLVE, 1255 23RD STREET, N.W. SUITE 275
WASHINGTON, D.C.

The Topic of this meeting was Presentation and Discussion of the Fish Lifecycle Detailed Review Paper (DRP).

_____/s/_____ _____/s/_____

Jane Scott Smith, DFO
Endocrine Disruptor Methods Validation Subcommittee under the National Advisory Council for Environmental Policy and Technology
Date: 2/6/2003

Joseph Merenda, Chair
Endocrine Disruptor Methods Validation Subcommittee under the National Advisory Council for Environmental Policy and Technology
Date: 2/13/2003

TABLE OF CONTENTS

EDMVS Members in Attendance at the December 2002 Teleconference

Attended in Person at RESOLVE

Joseph Merenda, Chair
U.S. EPA

William Benson, Ph.D.,Co-Chair
U.S. EPA

William Stokes, D.V.M.
NIEHS

Attended Via Telephone

Theodora Colborn, Ph.D
World Wildlife Fund

Robert Combs, Ph.D.
Fund for Replacement of Animals
In Medical Experiments

Rodger D. Curren, Ph.D.
Institute for In Vitro Sciences, Inc

J. Charles Eldridge, Ph.D.
Wake Forest University

Robert J. Kavlock, Ph.D.
U.S. EPA

William Kelce, Ph.D.
Pharmacia Corporation

Nancy K. Kim, Ph. D.
NY State Department of Health

Timothy Kubiak, M.P.H.
U.S. Fish and Wildlife Service

Gerald A. LeBlanc, Ph.D.
North Carolina State University

Ron Miller, Ph.D
The Dow Chemical Company

Susan C. Nagel, Ph.D.
University of Missouri-Columbia

James W. "Willie" Owens, Ph.D.
The Procter & Gamble Company
(on temporary detail to OECD)

Thomas L. Potter, Ph.D.
USDA-Agriculture Research Service

Theodore H. Schettler M.D., MPH
Science & Environ. Health Network

Shane A. Snyder, Ph.D.
Southern NV Water Authorilty

James T. Stevens. Ph.D.
Wake Forest University

Glen Van Der Kraak, Ph.D.
University of Guelph

James D. Yager, Jr., Ph.D.
Johns Hopkins University

Facilitator
Paul De Morgan
RESOLVE

Designated Federal Official
Jane Scott Smith
Office of Science Policy and Coordination

Presenter

Presenter

Les Touart
EPA, OSCP

Public Oral Commenters

Public Commenters

Rick Becker
ACC

Troy Seidle
PETA

NOTICE

This meeting summary has been written as part of the activities of the National Advisory Council on Environmental Policy and Technology (NACEPT), Endocrine Disruptor Methods Validation Subcommittee (EDMVS). This meeting summary has not been reviewed for approval by the United States Environmental Protection Agency (Agency) and, hence, the contents of the meeting summary do not necessarily represent the views and policies of the Agency, nor of other agencies in the Executive Branch of the Federal government, nor does mention of trade names or commercial products constitute a recommendation for use.

The NACEPT EDMVS was established in partial fulfillment of a Congressional statute. When Congress amended the Federal Food Drug and Cosmetics Act (FFDCA) in the Food Quality Protection Act (FQPA) of 1996, it directed the U.S. Environmental Protection Agency (EPA) to develop a screening program to determine whether certain substances may have hormonal effects in humans. To ensure that EPA has the best and most up-to-date advice available regarding the validation of the screens and tests in the EDSP, EPA established the Endocrine Disruptor Methods Validation Subcommittee (EDMVS) under the NACEPT. The EDMVS provides independent advice and counsel to the Agency through NACEPT on scientific and technical issues related to validation of the EDSP Tier I and Tier II assays, including advice on methods for reducing animal use, refining procedures involving animals to make them less stressful, and replacing animals where scientifically appropriate. The EDMVS held their first meeting in October of 2001, their second meeting in December 2001, and their third meeting in March 2002. The fourth meeting of the EDMVS was conducted as an international teleconference in June 2002. The fifth meeting was in July of 2002 and sixth was conducted as an international teleconference in December of 2002.

The December 4, 2002 open meeting (teleconference) of the EDMVS was announced in the Federal Register on November 14, 2002 (Volume 67, Number 220). Further information about NACEPT EDMVS meetings and activities can be obtained from its website at http://www.epa.gov/scipoly/oscpendo or the OPPT Docket at (202) 566-0280. INTERESTED PERSONS ARE INVITED TO CONTACT Jane Smith, EDMVS Designated Federal Official (DFO), via e-mail at smith.jane-scott@epa.gov.

National Advisory Council for Environmental Policy and Technology (NACEPT)

Endocrine Disruptor Methods Validation Subcommittee (EDMVS)

Meeting by Conference Call
December 4, 2002
10:00 a.m. – 12:00 noon EST

Proposed Agenda

Members of the public may join this conference call in person at the conference room in the RESOLVE offices at 1255 23rd St. NW, Suite 275, Washington, DC. To register to participate by phone, please contact Jane Smith, designated federal official for the EDMVS, at smith.jane-scott@epa.gov or (202) 564-8476. Also note that members of the public who would like to make comments during the conference call need to contact Ms. Smith prior to the meeting.

Meeting Objective:

- Provide comments and advice on the Fish Lifecycle DRP (Tier II).

10:00 – 10:05 Phoning in

10:05 - 10:10 Welcome and Opening Comments

- **Roll Call**
- **Overview of FACA Requirements**

10:10 – 10:30 Fish Lifecycle DRP (Tier II) Presentation
Dr. Les Touart, Office of Science Coordination and Policy (OSCP), EPA

10:30 – 11:40 Discussion on Fish Lifecycle DRP

The purpose of this DRP is to define the basis and purpose of the proposed two generation test for evaluating endocrine effects. The DRP summarizes, explains, and documents decisions regarding the relevant principles, methods, and techniques recommended for an initial protocol with four candidate species of fish (fathead minnow, zebrafish, medaka, and sheepshead minnow), and identifies issues that might require prevalidation studies to adequately address information gaps. Please use the following questions as a guide for your feedback to EDSP:

1. Does the EDMVS agree that the two-generation method recommended and applicable to four species of fish is appropriate?
2. Does the EDMVS agree that prevalidation should evaluate the increased sensitivity of a two-generation design over the existing fish full life-cycle standard practice?
3. Does the EDMVS agree that prevalidation should demonstrate the sensitivity and reproducibility for each species in the recommended protocol?

4. Does the EDMVS have suggestions to improve the DRP?

11:40 – 11:55 Public Comment

Members of the public who would like to make comments during the conference call must contact Jane Smith, designated federal official for the EDMVS, at smith.jane-scott@epa.gov or (202) 564-8476. Members of the public are requested to focus their comments on issues related to the Fish Lifecycle DRP to the extent possible.

11:55 – 12:00 Next Steps

12:00 Adjourn

Introduction

The Office of Science Coordination and Policy's Endocrine Disruptor Screening program established the Endocrine Disruptor Methods Validation Subcommittee (EDMVA) under The National Advisory Council for Environmental Policy and Technology (NACEPT). All of the subcommittee meetings are held in accordance with the Federal Advisory Committee Act and are always open to the public with time available for public comment. The first EDMVS meeting was held in October 2001. That initial meeting brought the members together to review the mission statement, the operating procedures and discuss subcommittee roles and responsibilities. The second meeting, held in December 2001, was the first time the subcommittee members were presented with specific questions regarding assay protocols. The third meeting, held March 2002, continued discussions on protocols as well as some discussions on the validation process, Core Chemicals, 'low dose' and means of assessing human health effects. The fourth meeting, held as a teleconference, was wholly concerned with the Steroidogenesis assay. The fifth meeting continued discussions on protocols as well as some discussions on the EDMVS work plan, the criteria for screens and general dose setting issues.

Endocrine Disruptor Methods Validation Subcommittee (EDMVS)
Meeting by Conference Call
December 4, 2002

Meeting Summary

- Final -

On December 4, 2002, the U.S. Environmental Protection Agency (EPA) convened a meeting of the Endocrine Disruptor Methods Validation Subcommittee (EDMVS) by conference call. The objective of the meeting was to provide comments and advice on the *Draft Detailed Review Paper on a Fish Two-Generation Toxicity Test*. The meeting took place in Washington, DC; however, many of the EDMVS members, as well as some members of the public, participated by phone.

Copies of presentation slides and other materials distributed at the meeting may be obtained by contacting Jane Smith, the designated federal official for EDMVS, at smith.jane-scott@epa.gov or 202/564-8476. The materials also are available on the EPA website at http://www.epa.gov/scipoly/oscpendo/edmvs.htm. EPA has established an administrative record for this meeting under docket control number OPPT-2002-0059. The docket is available for public viewing at the EPA Docket Center, Rm. B102 – Reading Room, EPA West, 1301 Constitution Ave., NW., Washington, DC. The center is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays.

The center's phone number is (202) 566-1744 and the telephone number for the OPPT Docket, which is located in the EPA Docket Center, is (202) 566-0280.

I. Opening Comments, Roll Call, and Agenda Review

Paul De Morgan, senior mediator with RESOLVE, welcomed EDMVS members and other participants to the meeting and thanked them for attending by phone or in person. He introduced Joe Merenda, Director of the Office of Science Coordination and Policy (OSCP) and new chair of the EDMVS. Mr. Merenda highlighted the Endocrine Disruptor Screening Program (EDSP) as one of the most visible and critical of that office's functions, and he expressed his enthusiasm for being involved with the subcommittee and learning more about the issues.

Jane Smith, designated federal official for the EDMVS, explained that the meeting was being held in accordance with the Federal Advisory Committees Act (FACA) and all materials distributed would be available through the docket and on the website. She invited anyone experiencing problems with the website or other concerns to contact her. She asked participants to send her the comments. All written comments will be posted on the EDSP website at the address noted above.

Mr. De Morgan did a roll call of EDMVS members and public participants who had registered and asked other participants to announce their names. (Please see attachment A for a list non-member meeting attendees.) He asked subcommittee members to let him know at the end of the conference call if the two-hour time period for the discussion was insufficient to address all topics. He encouraged participants to submit written comments to Ms. Smith if they were unable to raise them on the call. He then reviewed the meeting agenda.

II. Fish Two-Generation Toxicity Test DRP

Les Touart, OSCP, gave a slide presentation on *A Fish Two-Generation Toxicity Test Detailed Review Paper* (DRP). He noted the methods used in the DRP analysis, including an online literature search, interviews with experts, and an external/internal peer review. He explained existing fish lifecycle tests do not address relevant biochemical, morphological, and behavioral endpoints. Further, transgenerational endocrine effects are not assessed in current tests. For these reasons, EPA recommends replacing existing lifecycle tests with a two-generation test that addresses these factors. Dr. Touart covered characteristics and strengths and weaknesses of the fathead minnow (*Pimephales promelas*), medaka (*Oryzias latipes*), zebrafish (*Danio rerio*), and the sheepshead minnow (*Cyprinodon variegates*) test species. Other presentation comments included the following:

- For candidate replacement tests, the principal route of administration of chemical

exposure is aqueous, other optional routes include dietary, intravascular, and intraperitoneal injection.
- Measurement endpoints include morphological alterations, reproductive performance, and biochemical measures including vitellogenin induction.
- Vitellogenin is measured using direct and indirect quantification of vitellogenin protein, quantification of vitellogenin mRNA, and mass spectrometry.

- Candidate protocols include partial life-cycle, full life-cycle, multigeneration, and two-generation tests, and the DRP recommends moving forward with the proposed two-generation protocol.
- This test exposes the adult P, full F1 generation, and measures F2 viability, measuring biological endpoints for the adults and both subsequent generations.

Dr. Touart noted the significant data gaps that exist but commented that information is improving quickly. He also outlined implementation considerations, including prevalidation studies and validation of the study design through interlaboratory comparisons.

Following his presentation, Dr. Touart answered questions of clarification from EDMVS members. He explained that the concept of the partial lifecycle test is similar to the short term reproduction test that uses breeding groups and exposure information to guide the selection of spawning groups for exposure and helps to reduce variability.

The purpose of the protocol, as a tier 2 test, is defined as definitively evaluating endocrine potential and adverse effects of a compound on the lifecycle, including survival, ability to reproduce, and growth. Further, transgenerational factors such as the viability of offspring are intended to be tested. This protocol will address endpoints relevant for predicting population effects, which are an important component for ecological risk assessments. The protocol would be triggered for a compound when the tier 1 screen or other available information indicate a potential for interfering with hormone activity.

A member asked whether there are differences between EPA's approach and that of OECD, in that OECD has a 3-tier approach with a step between mechanistic screens and two-generation tests. Dr. Touart explained there is not discordance, as OECD has not established an official tiered framework. While endpoints used at the screening level are still under discussion, any indication that a compound will impact the endocrine system of a fish species will trigger a further evaluation of that compound. He agreed that additional information may sometimes be needed before beginning a two-generation test, and an intermediate tier could help with range- finding. However, a compound found to act on the endocrine system will require a definitive test such as the two-generation test, regardless of whether a partial lifecycle test or other intermediate level test is run first. The member disagreed that a two-generation test would be necessary in all cases.

III. EDMVS Member Discussion of the Fish Lifecycle DRP

Mr. De Morgan referred members to the discussion questions listed in the agenda and asked for their input, noting that the first was a two-part question (as shown below). Because of interrelated nature of the questions, EDMVS members touched on all four questions throughout the course of the conference call. Thus, the comments summarized under each of the questions below may overlap across questions.

1a. Does the EDMVS agree that the two-generation method recommended in the DRP is appropriate and an improvement over the previous fathead minnow tests?

A member emphasized the importance of assessing egg or embryo exposure to the chemical and expressed a concern that 14-21 days of exposure would not be sufficient to establish steady state for more lipophilic chemicals, and therefore would not expose the egg or embryo. He noted that the multigeneration test would better handle egg/embryo exposure. Alternatively, the two-generation test could forego the F2 generation and instead lengthen parental exposure and then take the F1 generation to full reproductive maturity. Another member noted that the multigeneration test has the advantage of exposing all lifecycle stages.

A member suggested comparing the two-generation test with existing protocols to better understand the unique benefits of the proposed test. Dr. Touart responded that EPA is already considering doing an evaluation of the two-generation and full lifecycle test. He also said they could consider conducting additional comparisons.

One member commented that since fish are not covered by the Animal Welfare Act, these validation studies should be conducted in accordance with the Public Health Service Policy on the Humane Care and Use of Laboratory Animals, which is applicable to all vertebrate species. He added that this would ensure that all animal care and use was reviewed and overseen by an animal care and use committee, and that such care and use was accomplished in accordance with the National Research Council Guide for the Care and Use of Laboratory Animals.

1b. Are the four species (fathead minnow, medaka, zebrafish, and sheepshead minnow) appropriate candidates for this test?

A member asked why it is necessary to use four species of fish, and, if all four were used, how data would be interpreted. Another member pointed out that there are international species preferences, and the prevalidation stage is the time to determine how the different species compare. Dr. Touart explained that the medaka and zebrafish were included as candidates because of their favor in other countries. The sheepshead minnow was added for practicality, as this species has a historical context and brings in the ecological context of estuarine/marine effects. Dr. Touart highlighted the importance of maintaining cross-species comparisons and extrapolations. These species are advantageous both in EPA's familiarity with them as well as their potential to be

accepted and compared internationally. He noted that existing methodologies are somewhat limited in their international applicability. A member added that testing the protocol with all four species early on will result in more information and, hopefully, fewer animals would be needed once the test is validated and part of the battery.

A member suggested conducting a retrospective review of existing data to determine what is known about comparative sensitivity between species. A pilot study could also help determine differences in sensitivity for effects at low concentrations for weak acting chemicals and could save many animals in later testing. A member agreed that governments should be able to detect whether there are species-specific effects, and another EDMVS member highlighted the importance of ensuring that data collected will have mutual acceptance in the international community.

One member said that EPA should consider using species for tier 2 tests for which data has been collected in tier 1 screens, especially if the sensitivity of all four species is comparable. Gary Ankley, EPA, said that there is no reason to suspect the species would differ greatly with respect to sensitivity, especially when tested in conserved systems. Differences in sensitivity would likely be related to experimental design rather than innate differences in the species. Dr. Ankley shared that the decision depends mostly on practicality and geopolitical preferences for particular species.

2. Does the EDMVS agree that prevalidation should evaluate the increased sensitivity of a two-generation design over the existing fish full lifecycle standard practice?

A member suggested that the partial lifecycle test be considered along with the two-generation design. Another member commented that the partial lifecycle test does not have full exposure for maternal uptake and exposure to offspring. Dr. Touart referenced the previous suggestion to investigate the multigeneration test as well. Another member agreed that the multigeneration test should be evaluated along with the two-generation test, as it reflects co-exposure to other types of information such as salinity levels in the aqueous environment.

A member supported using the historical database for the partial and full lifecycle test, noting that there is prevalidation information available for full lifecycle tests in the fathead and sheepshead minnows. Rather than proposing new compounds, he asked EDMVS members to share their thoughts about using the existing database of compounds to conduct multigeneration or two-generation tests. One member encouraged this plan, adding that results should be compared to those of early life stage test results to determine the added value of the two-generation test. Another member raised the issue that previous evaluations, such as early life stage studies, did not include endocrine endpoints.

Members asked about the contents of the database, conclusions that can be drawn from it, and the general practicality of using these data. Dr. Touart explained that the data reviews are secondary information within EPA's files, but the actual studies would have to be released from the companies involved. He added that there have been

previous reviews of EPA's fish lifecycle data set in combination with other data sets, and those discussions and conclusions could be made available to the subcommittee. Dr. Touart also called the subcommittee's attention to EPA's draft proposal to OECD on the fish two-generation guideline, which highlights EPA's plan to make ample use of international resources and depend as much as is feasible on retrospective analyses.

3. Does the EDMVS agree that prevalidation should demonstrate the sensitivity and reproducibility for each species in the recommended protocol?

The group began by discussing routes of exposure. Members commenting on route of exposure indicated support for aqueous exposure as the most relevant and practical route, especially considering that the preponderance of data available is based on this route of exposure. Regarding other routes considered by EPA (dietary and direct injection techniques), Dr. Touart indicated that these exposures would be used only in a special case. He agreed that, in general, aqueous exposure would be the most ecologically relevant route.

A member asked whether the fate of chemicals would be tested to determine whether they are detectable in water or food. Dr. Touart responded that if a compound has no strong exposure potential, it is unlikely that it would move into tier 2. He reiterated that EPA would focus on the aqueous route of administration in prevalidation because the majority of compounds would act through that route. A member suggested that using dietary exposure would require a validation or prevalidation study separate from tests using aqueous administration.

Some members revisited the issue of steady state, pointing out that for chemicals with special characteristics, such as lipophilic compounds, the route and length of exposure requires unique consideration. One member suggested that EPA consult the literature on this matter.

Mr. De Morgan summarized members' suggestions, noting that EPA should be explicit about steady state and its relevance to routes of exposure when completing protocols. A member added that EPA should be aware of any variability related to whether test subjects reach steady state and thus the comparability of endpoints.

4. Does the EDMVS have suggestions to improve the DRP?

Members asked EPA to include comparisons with database information relevant to the protocol in the DRP, as these comparisons would be helpful in getting a sense of the variability in endpoints. One member noted that some existing data are reflected in the DRP, and these references should be included. Dr. Touart explained that some data were from EPA studies and can be shared. EPA can also share their reviews of data from secondary research, but the actual studies would have to be released by registrants. Before proceeding, EPA would need to determine the relevance of existing data to this test.

A member suggested that bringing closure to the discussion of different protocols would improve the DRP. He added that some of the vitellogenin techniques seem time consuming and asked whether a more rapid method was available for tests. Dr. Touart agreed that the DRP could do a more thorough job of drawing conclusions. Regarding vitellogenin, Dr. Touart explained that there is ongoing research to compare methods.

In response to a question on steroid receptors, Dr. Touart encouraged members to send comments. These and any other comments from the EDMVS or the public would be most helpful if received by the first week of January.

IV. Public Comment

Rick Becker, American Chemistry Council
Dr. Becker commented that geopolitical realities need to be addressed, and EPA should take a leadership role with OECD in discussing comparability. He stressed that mutual acceptance of data is critical, and EPA should plan for it up front. A comparison of the protocols is needed and must determine the value added of the longer, more expensive studies. Dr. Becker asked EPA to consider both type 1 (false-positive) and type 2 (false-negative) errors. EPA also should clarify the objective of the study as this will affect the measurement of successful validation.

Troy Seidle, People for the Ethical Treatment of Animals
In regard to question 1, Mr. Seidle commented that, in principle, EPA should evaluate the sensitivity of a two-generation design over the existing standard practice. EPA must be able to demonstrate a significant need as well as "value added" before a new test or endpoint is considered as a regulatory requirement. That being said, EPA's current requirement for a multiplicity of animal tests for the same or similar endpoints is redundant and unacceptable. As a matter of policy, EPA program offices must better coordinate their chemical assessment efforts in order to prevent duplication. Mr. Seidle said that in regard to question 2, from a strictly scientific perspective, the answer is yes, because it would be unwise to assume that data from one species are generalizable to another. On a policy level, however, it would be inappropriate for EPA to proceed into prevalidation of a test of this magnitude with four species; a single species is more than enough. In conclusion Mr. Seidle asked that immediate consideration be given to reducing the scope of Tier 2 to the single most sensitive species, and discontinuing efforts to develop and validate multigenerational studies in others.

V. Next Steps

Dr. Touart summarized some of the comments he heard from the EDMVS members:
- EPA should evaluate whether the two-generation protocol is sufficient and should consider multigenerational protocol in order to cover exposure potential for eggs and embryos.
- Species comparisons within the two-generation method would be useful, as would comparisons to show the advantages of this protocol over lifecycle, partial lifecycle, and multigeneration tests.

- EPA should consider geopolitical preferences in choosing a test species. A comparison across species would be valuable.
- The aqueous exposure route seems most relevant. The DRP should include a discussion of the circumstances under which other exposure routes might be used.

Mr. De Morgan thanked Dr. Touart for his presentation and others for their comments and discussion. Mr. Merenda also thanked the members for the productive discussion. Noting that Ms. Smith was about to present the proposed meeting schedule, he asked members to remember that EPA is striving to balance the desire for momentum with the reality of needing to have information ready for each meeting in order to use members' time as efficiently as possible.

Mr. De Morgan asked members whether they felt the call had given them adequate time to discuss the DRP. Several members noted they had additional comments and could have used more time for the discussion. Some said they would submit written comments to Ms. Smith. Dr. Touart noted that comments would be most useful if they were received by January 10, 2003. Mr. De Morgan suggested that EPA should review the comments and then consider whether it would be beneficial to hold a second conference call or include further discussion of this DRP on the agenda of a future in-person meeting.

Proposed Future Meeting Schedule

Ms. Smith presented the following proposed meeting schedule and asked members to reserve the dates, noting that the topics for each meeting are still tentative.

- June 4-5, 2003 (2 full days)
    - June 4 - Mammalian 2-generation (Tier II): One generation extension study results; Avian Two Generation Assay (Tier II) Detailed Review Paper
    - June 5 – Steroidogenesis Assay (Tier I): The Results of the Optimization of the Protocol using sliced testes ; Aromatase: The results of the optimization and performance comparison of the assay using placental tissues (porcine, human, bovine) and human recombinant receptor

- August 19-21, 2003 (2 1/2 days)
    - Aug 19 (half day) - Fish Short Term Reproduction Assay (Tier I): Evaluation of Vitellogenin Methods in Zebrafish & Medaka study results; Fish Reproductive: Evaluation of Vitellogenin Methods in Fathead Minnow study results
    - Aug 20 - Fish Short Term Reproduction Assay (Tier I): Comparative Evaluation of the Fathead Minnow Assays study results
    - Aug 21 - Pubertals male and female: Multi-dose demonstration study results; Pubertals male and female: Multi-chemical Array study results

The meeting was adjourned at noon.

Attachment A

Non-Members Who Joined by Phone

Gary Ankley, EPA
Karin Bentley, DuPont Crop Protection
Ron Biever, SpringbornSmithers Laboratories
Michael Blanton, Battelle
Karen Bredam
Scott Brown, National Water Research Institute
Kristen Brugger, Crop Life of America
Ralph Cooper, EPA
Paul De Morgan, RESOLVE
Norma Domey, Environment Canada
Beth Doyle, EPA
Reinhart Fischer, Bayer Crop Science
Jerry Goldman, EPA
Tilghman Hall, Bayer Corporation
Charles Harper
Kevin Henry
Gary Henshaw
Dave Houchens, Battelle
Jerry Johnson, Battelle
Susan Laws, EPA
Ellen Mahaich, Rhodia
Miriam Medina-Vera, EPA
Claudia Olivieri, BASF
Troy Seidle, People for the Ethical Treatment of Animals
Ann Skillman, Battelle
Tim Springer, Wildlife International
Tammy Stoker, EPA

Non-Members Who Joined the Meeting at the RESOLVE Conference Room, Washington, DC

Elaine Francis, EPA
Rick Becker, American Chemistry Council
Sue Euling, EPA
Sally Grady, EPA
Jim Kariya, EPA
Sara Litke, RESOLVE
Rich Liroff, World Wildlife Fund
Joe Nash, EPA
Kazuhiko Nishroka, Japan External Trade Organization
Jennifer Peyser, RESOLVE
Greg Schweer, EPA

Jane Smith, EPA
Kris Thayer, Environmental Working Group
Gary Timm, EPA
Les Touart, EPA
Phil Zahodiakin, CRC Press, Pesticide and Toxic Chemical News